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Procedure for Data Validation in the Microbiology Laboratory

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1 Scope and Application

1.1 The Microbiology Laboratory has specific procedures set up to validate all analytical data produced. These procedures establish specific requirements for the review and validation of analytical data at the analyst, supervisor, manager, and quality assurance staff levels. All data is fully validated prior to reporting. The validation of each sample is recorded in the LIMS.

1.2 There are separate, slightly different procedures on Data Validation in the Bacteriology and Protozoan Laboratories.

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2 Definitions

2.1 Refer to Chapter 3 of the Georgia EPD Laboratory Quality Assurance Manual for Quality Control Definitions.

3 Quality Control

3.1 Refer to A.5 –Method Summary, Calibration, Calculations, and Data Quality Objectives; Chapter 5 – Containers, Preservation Techniques, and Holding Times; Chapter 13 – LIMS Operation; and Chapter 15 – Sample and Data Validation.

4 Procedure

Data Validation in Bacteriology Laboratory

4.1 Receiving and Processing of Samples

4.1.1 Data validation begins with careful examination of the sample I.D. form. As part of the validation process, scientists and laboratory supervisors ensure that:

4.1.2 The sample I.D. form matches the sample bottle.

4.1.3 The sample I.D. form has been properly and completely filled out. It is very important that there is a proper collection date and time on the slip because analysis is time critical.

4.1.4 The case card pulled for the sample matches the system I.D. number on the I.D. form.

4.1.5 The sample number stamped on the bottle matches the number stamped on the I.D. form.

4.2 Prior to Sample Analysis

4.2.1 Supervisors Red-Mark or Validate each I.D. form for correctness and instruction by making sure:

4.2.2 System I.D. number on form matches that on case card.

4.2.3 Sample number on form matches that entered on case card.

4.2.4 Date and time of collection are correct.

4.2.5 Marks the type of sample – routine, repeat, replacement, special, source approval, etc.

4.2.6 Informs scientist of anything special about the sample run and gives the okay to discard bottles after testing.

4.2.7 Scientists ensure that samples are prioritized according to holding times to ensure analysis within recommended holding time for compliance purposes.

4.3 Sample Analysis

4.3.1 During the analysis of samples, scientists and supervisors ensure that:

4.3.2 Test bottle matches test sample.

4.3.3 100 ml of sample per test (Colilert, Multiple Tubes, MF) using appropriate media.

4.3.4 There are negative and positive controls per run, per method requirements.

4.3.5 There is proper documentation of incubation times, analyst's initials, lot numbers and etc.

4.3.6 Each I.D. slip is stamped with analyst's initials and analysis start time.

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4.4 Data Entry into LIMS

4.4.1 Scientists, Supervisors, and Secretaries ensure that:

4.4.2 Samples are correctly logged into Labworks.

4.4.3 Samples are QA/QC batched into Labworks.

4.4.4 A worksheet and labels are printed after sample run is batched.

4.4.5 I.D. slips are stamped with analyst's initials and analysis start time.

4.4.6 Labels are correctly matched and placed on I.D. slips.

4.5 Recording and Interpretation of Results

4.5.1 Scientists and Supervisors ensure that:

4.5.2 Samples are read after a minimum of 24 hours of incubation.

4.5.3 Test bottle matches I.D. form.

4.5.4 Test result matches test bottle/I.D. form.

4.5.5 Test results match sample number/worksheet.

4.6 Reporting of Results into LIMS

4.6.1 Results are interpreted and recorded by the analysts to ensure that all quality assurance requirements are met for the method before data is entered into Labworks.

4.6.2 Scientists and Supervisors ensure that:

4.6.3 Sample results on worksheet match those for sample run that is entered into computer.

4.6.4 Correct information, such as analysis start time and analyst's initials, is properly entered.

4.6.5 Sample data saved for each entry and worksheet filed for final validation by supervisor.

4.7 Quality Control

4.7.1 Scientists and Supervisors ensure that:

4.7.2 All prepared media and dilution water is tested prior to use as per Standard Methods.

4.7.3 The effectiveness of the UV boxes are checked monthly.

4.7.4 The quality of the distilled water used by the lab is checked monthly.

4.7.5 The identification of bacteria by Colilert is accurate by performing API weekly to confirm and identify bacteria in the same water sample.

4.7.6 Temperatures are read from NIST certified thermometers twice daily in all operating water baths, incubators and refrigerators.

4.7.7 Logs are appropriately documented for Quality Assurance.

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4.8 Final Validation of Results

4.8.1 After samples have been analyzed and reported into Labworks, a final validation check is performed by the laboratory supervisor by:

4.8.2 Checking Valque (LIMS) for samples to be validated.

4.8.3 Accounting for each sample in Valque.

4.8.4 Verifying sample results on worksheet match those in Valque.

4.8.5 Notifying analyst if result or entry is incorrect.

4.8.6 Making modifications if needed.

4.8.7 Validating and exporting results to DWP and Network Server.

4.8.8 Copying validation sheets (Valques) and placing in logbook and giving a copy to secretary for printing of reports. Validation sheets are also stamped with name and date of person validating.

4.9 Printing of Reports and Unsatisfactory Logs

4.9.1 Supervisors and Manager ensure the following:

4.9.2 Generation and printing of reports by secretaries.

4.9.3 Generation of Unsatisfactory Reports by secretaries.

4.9.4 Check Unsatisfactory Reports/Sheets against I.D. forms for correctness. Ensure that reports are faxed to DWP and regions.

4.9.5 Copy of Unsatisfactory Sheet placed in logbook.

4.10 Paperwork/Reports

4.10.1 Scientists and Supervisors ensure that:

4.10.2 All printed information on report matches that on I.D. form.

4.10.3 If corrections are made, a corrected copy of report is mailed.

4.10.4 If required, a Corrective Action Number is assigned and properly documented.

Data Validation in Protozoan Lab

4.11 Processing of Samples

4.11.1 Data validation begins with careful examination of the sample identification form. As part of the validation process, Scientists and Laboratory Supervisor ensure that:

4.11.2 The sample's identification label matches the chain-of-custody and identification form accompanying sample.

4.11.3 The sample receipt temperature is recorded on the chain-of-custody form.

4.11.4 The sample identification form has been properly completed. It is very important that there is a proper collection date and time on the slip because analysis is time critical.

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4.11.5 Labels are attached to corresponding sample forms. (Protozoan samples are logged in by the Receiving Lab through the Chemistry Database. A unique lab number is generated and labels are printed for each sample.)

4.11.6 A lab benchsheet is created and the correct identification label is placed on it.

4.12 Prior to Sample Analysis

4.12.1 Prior to analysis, Scientists ensure that:

4.12.2 Samples are prioritized according to holding times to ensure analysis within recommended holding time for compliance purposes.

4.12.3 Ten liters of sample is poured into a clean carboy. The tag is removed from cubitainer and placed on the carboy.

4.12.4 Thirty-five to fifty mls of sample is poured from original cubitainer into a labeled centrifuge tube. This tube is stored in the refrigerator until later for the turbidity testing.

4.12.5 System filtered samples that have been shipped to the lab and refrigerated are allowed to sit on bench top and allowed to warm up prior to analysis.

4.13 Sample Analysis

4.13.1 During the analysis of samples, Scientists and Supervisor ensure:

4.13.2 Filtration, elution, concentration, IMS, staining procedures and reading of slides are all performed per method requirements and within method required

time constraints.

4.13.3 Proper documentation of sample analysis and reading of slides.

4.14 Recording and Interpretation of Results

4.14.1 Scientists and Supervisor ensure that:

4.14.2 Samples are QA/QC batched into Labworks.

4.14.3 A worksheet is printed after sample run is batched.

4.14.4 Test results matches those on benchsheet.

4.15 Reporting of Results into LIMS

4.15.1 Results are interpreted and recorded by the analysts to ensure that all quality assurance requirements are met for the method before data is entered into Labworks.

4.15.2 Scientists and Supervisors ensure that:

4.15.3 Sample results on worksheet match those for sample run that is entered into computer.

4.15.4 Correct information, such as analysis start time and analyst's initials, is properly entered.

4.15.5 Chlorine Status is modified on each sample.

4.15.6 Sample data saved for each entry and worksheet filed for final validation by supervisor.

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4.16 Quality Control

4.16.1 Method Blanks and OPR are performed weekly, before analyzing field samples. All results must be within acceptable range.

4.16.2 Temperatures are read from NIST certified thermometers twice daily in all operating incubators and refrigerators.

4.16.3 Logs are appropriately documented for Quality Assurance.

4.17 Initial Validation of Results

4.17.1 After samples have been analyzed and reported into Labworks, an initial validation check is performed by the Laboratory Supervisor by:

4.17.2 Checking Valque (LIMS) for samples to be validated.

4.17.3 Accounting for each sample in Valque.

4.17.4 Verifying sample results on worksheet match those in Valque.

4.17.5 Notifying analyst if result or entry is incorrect.

4.17.6 Making modifications if needed.

4.17.7 If required, a Corrective Action Number is assigned and properly documented.

4.18 Final Validation of Results

4.18.1 Manager's responsibilities include:

4.18.2 **Generating and printing reports**.
4.18.3 Checking report results and RL's against the benchsheets.
4.18.4 Printing and checking QA/QC Batch worksheets.
4.18.5 Ensuring any Corrective Action or sample comments written are correct.
4.18.6 Validating and exporting results to DWP and Network Server.

4.19 Paperwork/Reports
4.19.1 Scientists and Supervisors ensure that:
4.19.2 All printed information on report matches that on benchsheet.
4.19.3 If corrections are made, a corrected copy of report is mailed.

5 Calculations
N/A

6 Reference
6.1 Standard Methods for the Examination of Water and Wastewater, 19th Edition, American Public Health Association: Washington, D.C., 1995.

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